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PTO/SB/21 (09-04)

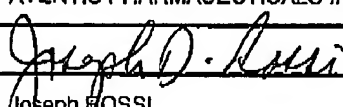
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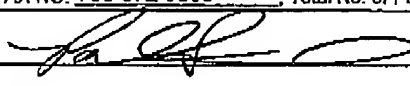
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TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Application Number	10/719,080
	Filing Date	November 21, 2003
	First Named Inventor	Michael GRAUPE et al.
	Art Unit	1626
	Examiner Name	Anderson, R.L.
	Attorney Docket Number	USAV2001/0082 US CNT
Total Number of Pages in This Submission	16	

ENCLOSURES (Check all that apply)		
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of
GRAUPE, et al.

Examiner: Anderson, R.L.

Art Unit: 1626

Application No.: 10/719,080

Filed: November 21, 2003

Title: **NOVEL COMPOUNDS AND
COMPOSITIONS AS CATHEPSIN
INHIBITORS**

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**INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. 1.56, 1.97 AND 1.98**

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Applicants submit herewith patents, publications, and other information of which they are aware, which they believe may be material, as defined in 37 C.F.R. 1.56(b), to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 C.F.R. 1.56(a). While the information referred to in this Information Disclosure Statement may be material pursuant to 37 C.F.R. 1.56(b), the filing of this Information Disclosure Statement is not intended to, pursuant to 37 C.F.R. 1.97(h), constitute an admission that any patent, publication or other information referred to is, or is considered to be, material to the patentability of this invention. Pursuant to 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information exists.

- ☒ (a) This Information Disclosure Statement is filed within the period set forth in §1.97(b) because it accompanies the new patent application submitted herewith, is filed within three months of the filing date of a national application or within three months of the date of entry of the national stage as set forth in §1.491 in an international application, or is believed to be filed before the mailing date of a first Office Action on the merits, whichever event occurs last. However, in the event that the first office action has been mailed, the Commissioner is authorized to charge any fees under 37 C.F.R. 1.17(p) or credit any overpayment to Account No. 18-1982.

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- ☐ (1) The undersigned attorney certifies that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement;
- ☐ (2) The undersigned attorney certifies that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned attorney after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of this statement; or
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A concise explanation of the relevance of some or all of the items listed on the attached PTO-1449 (modified) is as follows:

The items listed on pages 1-13 of the attached PTO-1449 have been previously submitted to the Patent Office or cited by the Examiners during the prosecution of the following patents or patent applications commonly owned by the assignees of record of the present case:

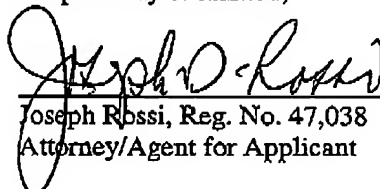
U.S. Patent Nos. 6,576,630, 6,506,733, 6,455,502 and 6,492,362; and

U.S. Patent Application Nos. 10/035,783, 10/478,632, 10/787,367, 10/418,183 and 10/294,526.

Therefore, a copy of the reference is not enclosed with this Information Disclosure Statement.

However, the applicant will furnish a copy of any listed reference, if so requested by the Examiner.

Respectfully submitted,


Joseph Rossi, Reg. No. 47,038
Attorney/Agent for Applicant

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Aventis Docket No. USAV2001/0082 US CNT

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Application Number	10/719,080
				Filing Date	11-21-2003
				First Named Inventor	GRAUPE
				Group Art Unit	1626
				Examiner Name	Anderson, Rebecca
Sheet	1	of	13	Attorney Docket Number	USAV2001/0082 - US - CNT

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
		4,927,809		STUBER, et al.	05-22-1990	
		5,424,325		ANDO, et al.	08-13-1995	
		5,486,623		ZIMMERMAN, et al.	01-23-1996	
		5,498,616		MALLANO, et al.	03-12-1996	
		5,847,135		BEMIS, et al.	12-08-1998	
		5,852,007		CHATTERJEE, et al.	12-22-1998	
		5,874,424		BATCHELOR, et al.	02-23-1999	
		5,998,390		RAMAMURTHY, et al.	12-07-1999	
		6,004,939		SPRUCE, et al.	12-21-1999	
		6,022,861		SCARBOROUGH, et al.	02-08-2000	
		6,114,310		CHAMBERLAND, et al.	09-05-2000	
		6,124,333		MILLER, et al.	12-26-2000	
		6,255,453		GYORKOS	07-03-2001	
		6,353,017		ALTMAN, et al.	03-05-2002	
		6,455,502		BRYANT, et al.	09-24-2002	
		6,476,026		BRYANT, et al.	11-05-2002	
		6,482,362		GRAUPE, et al.	12-10-2002	
		6,506,733		BUYSSE	01-14-2003	
		6,576,630		LINK, et al.	06-10-2003	

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Office ³	Number ⁴	Kind Code ⁵ (if known)			
		EP	EP 0272671		KRANTZ, et al.	06-29-1988	
		EP	EP 0291234		EDWARDS, et al.	11-17-1998	
		EP	EP 0355572		PAQUES, et al.	02-28-1990	
		EP	EP 0376012		ALBRIGHT, et al.	07-04-1990	
		EP	EP 0419883		HARA, et al.	04-03-1991	
		EP	EP 0536389		OKUBO, et al.	04-01-1993	
		EP	EP 0652009		DOVEY, et al.	10-05-1995	
		EP	EP 0754454		KOBAYASHI, et al.	01-22-1997	
		JP	JP 06192189		RYOICHI, et al.	07-12-1994	
		JP	JP 42009133		IRIKURA, et al.	05-06-1987	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Application Number	10/719,080	
			Filing Date	11-21-2003	
			First Named Inventor	GRAUPE	
			Group Art Unit	1626	
			Examiner Name	Anderson, Rebecca	
Sheet	6	of	13	Attorney Docket Number	USAV2001/0082 - US - CNT

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		ADAMS, et al., Potent and Selective Inhibitors of the Proteasom: Dipeptidyl Boronic Acids, Bioorganic & Medicinal Chemistry Letters, 8: 333-338 (1998).	
		ASHWORTH, et al., 4-Cyanothiazolidides as very potent, stable inhibitors of dipeptidyl peptidase IV, Bioorganic & Med. Chem. Letters, 8, Oxford, 6(22):2745-2748 (1996).	
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		BROMME, et al., Potent Inactivation of Cathepsins S and L, Biol. Chem. Hoppe-Seyler. vol. 375, No. 5, pp. 343-347, 1994.	
		CHATTERJEE, et al., D-Amino Acid Containing, High-Affinity Inhibitors of Recombinant Human Calpain I, Journal of Medicinal Chemistry, vol. 41, No. 15, p: 2663-2668 (1998).	
		COHEN, et al., Therapy of relapsing multiple sclerosis. Treatment approaches for nonresponders, Journal of Neuroimmunology, 98: 29-36 (1999).	
		DUFOUR, et al., Engineering nitrile hydratase activity into a cysteine protease by a single mutation, Biochemistry, US, Am. Chem. Soc., Easton, PA, 34(50):16382-16388 (1995).	
		EDWARDS, et al., Design, Synthesis, and Kinetic Evaluation of a Unique Class of Elastase Inhibitors, the Peptidyl a-Ketobenzoxazoles, and the X-ray Crystal Structure of the Covalent Complex between Porcine Pancreatic Elastase and Ac-Ala-Pro-Val-2-Benzoxazole, Journal of American Chemical Society, vol. 114, No. 5, p 1854-1863 (1992).	
		EVOLI, et al., abstract only, Drugs, 1996, 52(5), 662-70	

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		Filing Date	11-21-2003
		First Named Inventor	GRAUPE
		Group Art Unit	1826
		Examiner Name	Anderson, Rebecca
		Attorney Docket Number	USAV2001/0082 - US - CNT
Sheet	7	of	13

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		GOUR-SALIN, et al., Inhibition of papain by peptide nitriles: conversion of the nitrile group into other functionalities via the papain:nitrile thiomidate ester adduct, Can. J. of Chem, CA, National Research Council, Ottawa, 69(8):1288-1297 (1991).	
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		LI, et al., Aminoacylpyrrolidine-2-nitriles: Potent and stable inhibitors of dipeptidyl-peptidase IV (CD 26), Archives of Biochem. and Bioph., 323(1):148-154 (1995).	

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		LIPSHUTZ, et al., Chiral induction in originally racemic amino acid via 5-acyl and 5-acyloxyaminooxazoles, Isr. J. Chem. 27(1):49-58 (1986), abstract.	
		LIPSHUTZ, et al., Heterocycles as masked diamide/dipeptide equivalents. Formation and reactions of substituted 5-(acylamino)oxazoles as intermediates en route to the cyclopeptide alkaloids, . Am. Chem. Soc., 105(26):7703-7713 (1983).	
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		MARQUIS, et al., Potent dipeptidylketone inhibitors of the cysteine protease cathepsin, Chemical Abstracts, 7:4 581-588 (1999).	
		MCMATH, et al., Direct dialkylation of peptide nitriles. Application of the synthesis of 1-aminocyclopropane-1 carboxylic acid (Ace)-containing dipeptides, Bull. Soc. Chim. Fr. 134(1):105-110 (1997).	
		MORIYA, et al., Synthesis and Hypolipidemic Activities of 5-Thienyl-4-oxazoleacetic Acid Derivatives, sup.1, J. Med. Chem., 29: 333-341 (1986).	
		MOSER, et al., 130 Poly (dipeptamldinium)-Salze: definition und metoden zur preparativen herstellung. poly (dipeptamldinium) salts: definition and methods of preperation, Helvetica Chimica ACTA, CH, Verlag, Basel 69:1224-1262 (1986).	
		NIPPON, K., Patent Abstracts of Japan, Publication No. 63301868, 013(137)(1988), abstract.	
		NORTH, et al., Synthetic studies towards cyclic peptides. Concise synthesis of thiazoline and thiazole containing amino acids, Tetrahedron, 46(24):8627-8290 (1990).	
		OGILVIE, et al., Peptidomimetic inhibitors of the human cytomegalovirus protease, Journal of Medicinal Chemistry vol. 40 No. 25 (1997).	

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Sheet	9	of	13	

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		PICKEN, et al., Inhibition of bovine cathepsin B by amino acid-derived nitriles, Biochemical Society Transactions, vol. 18, No. 2, p:316 (1990).	
		PLIURA, et al., Comparative behavior of calpain and cathepsin B, Biochem. J. vol. 288, pp. 759-762, 1992	
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		RIESE, et al., Essential Role for Cathepsin S in MHC Class II-Associated Invariant Chain Processing and Peptide Loading, Immunity, 4: 357-366 (Apr. 1996).	
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		SUAVE, et al., Carboxylmodified amino acids and peptides, I. An efficient method for the synthesis of monofunctionalized enamines and monofunctionalized methyl ketone derivatives from thioamides via episulfides and thioiminium salts, Tetrahedron Lett, 29:19 2295-2298 (1988).	
		SUZUE, S., Hepatic agents. I. Synthesis of aminocyl (and hydroxyacyl) aminoacetonitriles, Chem. and Pharm. Bull. (Tokyo) (1968), 16(8), 1417-32.	
		SUZUE, et al., Studies on Heptic Agents, Chem. Pharm. Bull. vol. 16, No. 8, pp. 1417-1432, Aug. 1968.	
		SUZUKI, et al., Synthesis of 2-Aryl-4-(3-thienyl)imidazole Derivatives with Antiinflammatory Properties .sup.1), Chem. Pharm. Bull, 34(8): 3111-3120 (1986).	
		TAO, et al., Inhibition of Calpain By Peptidyl Heterocycles, Bioorganic & Medicinal Chemistry Letters, 6:24 3009-3112 (1996).	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Filing Date	11-21-2003
		First Named Inventor	GRAUPE
		Group Art Unit	1626
		Examiner Name	Anderson, Rebecca
		Attorney Docket Number	USAV2001/0082 - US - CNT
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		THOMPSON, et al., Carboxyl-modified amino acids and peptides as protease inhibitors, J. Med. Chem., 29(1):104-111 (1986).	
		TSUTSUMI, et al., Synthesis and Structure-Activity Relationships of Peptidyl α-Keto Heterocycles as Novel Inhibitors of Prolyl Endopeptidase, Journal of Medicinal Chemistry, vol. 37, No. 21, p 3492-3502 (1994).	
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		, Derwent Abstract of Japanese Patent Application 06-192189, (Jul. 12, 1994).	

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		CHAPMAN, et al., Emerging Roles for Cysteine Proteases in Human Biology, Ann. Rev. Physiol.; 1997; 59; pp.63-88.	
		DRANOFF, et al., Cathepsin S Required for Normal MHC Class II Peptide Loading and Germinal Center Development, Immunity; 1999; 10; pp.197-208.	
		FENWICK, et al., Diastereoselective Synthesis, Activity and Chiral Stability of Cyclic Alkoxyketone Inhibitors of Cathepsin K., Bioorg. Med. Chem. Lett.; 2001; 11(2); pp.199-202.	
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		NAKAGAWA, et al., Impaired Invariant Chain Degradation and Antigen Presentation and Diminished Collagen-induced Arthritis in Cathepsin S-null Mice, Immunity; 1999; 10; pp.207-217.	
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		SHI, et al., Molecular Cloning and Expression of Human Alveolar Macrophage Cathepsin S, an Elastolytic Cysteine Protease, J. Biol. Chem.; 1992; 267; pp.7258-7262.	
		SINGH, et al., beta-lactams as Enzyme Inhibitors, IDrugs; 2000; 3(5); pp.512-517.	
		VILLADANGOS, et al., Cathepsin S Activity Regulates Antigen Presentation and Immunity, J. Clin. Invest.; 1998; 101(10); pp.2351-2363.	

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